

## ROVI lays the foundations for its future growth: it forecasts that its contract manufacturing business sales will double by 2030

- ROVI forecasts that its 2024 operating revenue will be multiplied by between 1.5 and 1.8 in six years, driven primarily by an increase in its contract manufacturing business sales.
- The company will reinforce its current position as one of the major global leaders in the fill and finish of injectables after expanding its installed capacity.
- ROVI expects the specialty pharmaceutical division to grow annually by a low-single-digit percentage in the period from 2024 to 2030, with Okedi® as the primary growth driver.
- The company plans to commence the next phases of the clinical development of Letrozole SIE<sup>1</sup> and three-monthly risperidone.

Madrid, 25 March 2025.- At its Capital Markets day today, Laboratorios Farmacéuticos Rovi, S.A. (BME: ROVI), a pan-European pharmaceutical company specialising and engaged in the research and development, contract manufacturing and marketing of small molecules and specialty biologics, announced important information on its financial performance, long-term strategy and growth prospects for the next six years. ROVI is committed to investing in its business in order to increase its production capacities and thus address the current imbalance between supply and demand, reinforce the company's internationalisation through Risperidone ISM® – its first proprietary innovative product based on ISM® technology –, and strengthen its product portfolio with new proprietary drugs based on ISM® technology, such as Letrozole SIE and three-monthly risperidone.

As a result of these investments, ROVI expects to multiply its operating growth by between 1.5 and 1.8 by the year 2030, driven primarily by its contract manufacturing

business (CDMO), which is forecast to double its sales to close to 700 million euros. Thus, ROVI becomes one of the world leaders with the largest capacities in the manufacture of high-value-added injectables (prefilled syringes, vials and cartridges).

In terms of EBTIDA excluding research and development expenses, ROVI forecasts that the 2024 figure will be multiplied by between 2.5 and 2.8, representing a bracket of from 583 million euros to 653 million euros, in 2030. This result reflects a sounder financial performance and an improvement in operating margins in the next six years.

These prospects fall within the framework of the potential growth in the CDMO market, which is favoured by the current imbalance between supply and demand in the pharmaceutical market, added to the increase in innovative products and biosimilars, which are leading the expansion of the injectables sector. At world level, injectables account for over 70% of all drugs, since they represent the fastest route of drug administration.

In this context, the CDMO market was estimated at around 185,000 million dollars in 2024, reflecting an increasing trend towards outsourcing the services of the fill and finish of injectables, as pharmaceutical companies seek to optimise their resources and focus on their core competencies.

In this environment, ROVI is positioned as a key player, taking advantage of its experience and fill and finish capacities to capitalise on the growth of this market. Over recent years, ROVI has invested in the vertical integration of its entire value chain, from production of the active ingredient to the fill and finish of the medicine.

With its recent investments and the expansions currently in progress, ROVI expects to substantially increase its high-value-added injectables capacity to ranges of between 625 million and 810 million prefilled syringes, between 140 million and 180 million vials and between 85 million and 110 million cartridges by the end of 2026. With this capacity, the company forecasts that its CDMO business sales will double by 2030, reaching around 700 million euros, with an estimated capacity utilisation ratio of between 70% and 75%.

"At the end of 2026, once we have our full capacity installed, our CDMO business will be among the world leaders in terms of capacity to manufacture high-value-added injectables in multiple formats. It is a very attractive business with a sound growth strategy," said Juan López-Belmonte Encina, ROVI's Chairman and Chief Executive Officer, for whom this division is one of the main contributors to the company's growth: "Since 2022, our CDMO business has not only doubled its capacity but has

also obtained FDA approval of all its contract manufacturing plants, which is a turning point for ROVI."

Regarding the specialty pharmaceutical business, the Company expects annual growth of a low-single-digit percentage between 2024 and 2030. The main growth driver in this business is Okedi® (Risperidone ISM®), the first product based on ISM® technology, which has been being marketed in Europe since 2022 and has also received marketing authorisation for Canada, Taiwan and Australia. This product is a long-acting injectable used to treat adult schizophrenia patients. According to the World Health Organisation, schizophrenia is a disease that affects 24 million people worldwide and long-acting injectables have become the benchmark for its treatment, since not only do they reduce the frequency with which the medication needs to be administered, but also favour treatment adherence.

ROVI expects that, given its differential characteristics, Risperidone ISM® will reach potential sales of between 100 and 200 million euros globally over the next few years and will become a significant player worldwide in the field of long-acting injectables to treat schizophrenia.

"Risperidone ISM® is one of ROVI's primary growth levers for the future. The favourable reception of this product in the European countries where it has been launched and the product's approval in new countries, such as Canada, Australia and Taiwan, opens up new opportunities for us in the field of long-acting injectables to treat schizophrenia globally. Innovation is one of ROVI's hallmarks and the ISM® platform provides new channels for growth. Along these lines, we are developing a three-monthly formula with which we also hope to provide these patients with a therapeutic alternative," said Juan López-Belmonte Encina.

Regarding the low-molecular-weight heparin (LMWH) business, ROVI aspires to become an international leader in this field. The company is focusing on optimising the costs associated to heparin production. In this respect, through the Glicopepton project, ROVI is continuing to invest to become self-sufficient in obtaining crude heparin and thus become a vertically integrated company in all the stages of LMWH manufacturing. Likewise, bemiparin is expected to continue consolidating its leadership in the Spanish market, where it currently holds a 31% share. At the end of 2024, this product had total sales of 96 million euros. It is the only second-generation low-molecular-weight heparin that guarantees effective 24-hour cover for all patient profiles with a daily dose, irrespective of the risk level. Additionally, ROVI developed an enoxaparin biosimilar, one of the first on the European market, that is currently

present in 41 countries. In 2024, this product achieved total sales of 145.2 million euros, representing a compound annual growth rate of 30% from 2018 to 2024.

Furthermore, ROVI has demonstrated its excellent track record in Spain in the distribution of licensed medicines, having launched over 20 products in the last 15 years, and is working on new agreements for the joint marketing of products in Europe. Likewise, ROVI is aware of the potential market opportunities represented by the acquisition of new medicines that allow it to expand its product portfolio.

At the same time, the company continues to advance in the artificial intelligence field, with the acquisition of a majority interest in CellsIA, a pioneering company engaged in developing assisted diagnostic solutions in the pathological anatomy area. This acquisition reinforces ROVI's commitment to moving forward in the diagnosis of diseases and providing cutting-edge solutions that improve the patients' quality of life.

## **Investments**

The company is making significant investments to become a global leader in the sterile fill and finish of injectables. This effort is intended to increase the current capacities and adapt to market needs. In this respect, ROVI is expanding the production capacity of its CDMO business and its services portfolio by adding new filling lines that enable it to manufacture cartridges and new assembly lines that allow cartridges to be inserted into pens and syringes into auto-injectors, improving the patient's experience when managing chronic diseases and complex treatments. The goal is to take advantage of the market opportunity to drive the long-term growth of the CDMO business and position ROVI as a global leader in the manufacture of high-value-added injectables.

Likewise, ROVI will continue to invest in launching and marketing Okedi® (Risperidone ISM®) and in low-molecular-weight heparins (LMWH), improving product traceability and generating cost efficiencies.

Regarding research and development investment, the company plans to commence the phase III clinical development of Letrozole SIE and three-monthly risperidone, two products based on ISM® technology that will expand the portfolio of products developed internally, in the fourth quarter of 2025. In this context, ROVI estimates that it will spend an average of between 40 and 60 million euros annually on research and development in the next six years.

## **Transition period**

For ROVI, 2024 and 2025 are years of transition, in which it is making significant investments that will lay the foundations for its future growth. The company is at a turning point, with a scenario that furnishes an opportunity for growth in forthcoming years as a result of the increase of its production capacity in the contract manufacturing business, its internationalisation through Okedi®, and the investment in research and development associated to the clinical development of Letrozole SIE and three-monthly risperidone.

"The ISM® technological platform will transform the company. Its advantages have been validated with Okedi® and we are currently working on two new clinical developments based on this technology: Letrozole SIE and three-monthly risperidone," said López-Belmonte.

Specifically, for 2025, ROVI reiterates its guidance and expects its operating income to decrease on the 2024 figure by a low-single-digit percentage. However, this guidance has been calculated considering certain factors that, although they could be relevant to the estimates, are difficult to specify at the present time.

## **About ROVI**

ROVI is a pan-European pharmaceutical company specialising and engaging in the research, development, contract manufacturing and licensing of small molecules and biological specialties. The company, in a continuous expansion process, has subsidiaries in Portugal, Germany, the United Kingdom, Italy, France and Poland and has a diversified marketing portfolio of over 40 products, among which its flagship product, bemiparin, now present in more than 60 countries all over the world, should be highlighted. Likewise, ROVI markets its enoxaparin biosimilar, developed inhouse, in Europe and this product is now present in 41 countries. ROVI is continuing to develop the ISM® technology platform, a leading-edge line of research in the field of prolonged drug release, with proven advantages. For more information, please visit www.rovi.es.